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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,954	06/25/2001	Hubert Jan Jozef Loozen	0/98414-US	9900

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	11

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/831,954	LOOZEN ET AL.
Examiner	Art Unit	
Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 09 July 2002.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-5 and 7 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-5 and 7 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

6) Other: \_\_\_\_\_.

## DETAILED ACTION

This Office Action is a response to Applicant's response filed on July 9, 2002 in Paper No. 10. Currently, claims 1-5 and 7 are pending in this application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lobaccaro et al. for reasons of record stated in the Office Action dated April 29, 2002.

Applicant's remarks filed on July 9, 2002 in Paper No. 10 with respect to this rejection of claims 1-5 and 7 made under 35 U.S.C. 103(a) of record stated in the Office Action dated April 29, 2002 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant asserts that Lobaccaro et al. only discloses these compounds as intermediated in a synthetic pathway. However, Lobaccaro et al. clearly discloses in the title and abstract therein that 11  $\beta$ -n-alkyl derivatives (11  $\beta$ -n-alkyl estradiol derivatives), i.e., estradiol having ethyl, butyl, or decyl as R<sub>11</sub>, which are homologs of the

instant compounds, are known estrogenic compounds. Compound 5b of Lobaccaro on page 2218, Table 1 on page 2219, Table 2 on page 2221, is not merely intermediated in a synthetic pathway in the scheme 1 therein, but the desired compound has been tested as a 11  $\beta$ -n-alkyl estradiol derivative to the estrogen receptor. See Table 1 and 2.

Therefore, as discussed in the previous Office Action, one of ordinary skill in the art would have reasonably expected that the instant compounds would have possess the similar activity as their homologs because of the substantially close structural relationship. It has been settled that the addition of  $\text{CH}_3$  or several  $\text{CH}_2$  groups to a known compound is not ordinarily patentable and *prima facie* obvious. See *In re Wood*, 199 USPQ 137. One of ordinary skill in the art would have reasonably expected that the instant compounds would be useful in the method for treating estrogen deficiency disorders, absent evidence to the contrary.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Napolitano et al. for reasons of record stated in the Office Action dated April 29, 2002.

Applicant's remarks filed on July 9, 2002 in Paper No. 10 with respect to this rejection of claims 1-5 and 7 made under 35 U.S.C. 103(a) of record stated in the Office Action dated April 29, 2002 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant's results shown in Table A of the specification at pages 14 herein have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive for the reasons below. Table A provides no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art since Table A provides no data in support of the conclusion that these compounds are agonist or antagonist to ER- $\alpha$  or EP- $\beta$ . Thus, the results in Table A is considered insufficient to establish any unexpected results.

Applicant is further requested to note that the instant claims are not limited to be agonist or antagonist to ER- $\alpha$  or EP- $\beta$ .

In view of the foregoing, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.  
Patent Examiner, AU 1617  
August 14, 2002

RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200